

REMARKS

I. CLAIM STATUS AND AMENDMENTS

Claims 1, 3-6 and 8-16 were pending in this application when last examined and stand rejected. Claims 2 and 7 were previously canceled. Claims 1, 3, 4, and 13 are amended to further clarify the intended subject matter. New claim 17 has been added which features subject matter previously recited in claim 13. No new matter has been added.

Applicants gratefully acknowledge the indication, at page 3 of the Office Action, that the previous rejections under 35 U.S.C. § 103 over FRIEDMAN et al. (US Patent No. 5,744,155) in view of RILEY (US Patent No. 5,055,303), and over FRIEDMAN et al. in view of SMOLINSKE (Handbook of Food, Drug and Cosmetic Excipients), and over FRIEDMAN et al. in view of RILEY and BONDA (US Patent No. 6,551,605), have been withdrawn.

II. CLAIM REJECTION - 35 U.S.C. § 112

At page 4, the Office Action rejects claim 14 under 35 U.S.C. § 112, second paragraph, as being indefinite. The Office Action points out that claim 1 recites both retinoid and phospholipid emulsifier as active ingredient and requires 10 to 15% by weight of the phospholipids emulsifier; therefore, it is unclear in dependent claim 14 how the active ingredient of retinoid and phospholipid emulsifier can be present in 0.01% to 0.5% in weight. Applicants respectfully traverse the rejection.

Amended claim 1 is directed to a microemulsion that includes a retinoid as active ingredient, a phospholipid emulsifier, and sodium hyaluronate. The phospholipid emulsifier is present in an amount ranging from 10 to 15% by weight. Claim 14 further specifies that the weight percentage of active ingredient is from 0.01% to 0.5% in weight. Claim 14 clearly defines the intended subject matter and satisfies the requirements of 35 U.S.C. § 112, second paragraph. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. CLAIM REJECTIONS - 35 U.S.C. § 103

At page 5, the Office Action rejects claims 1, 3-5 and 8-16 under 35 U.S.C. § 103(a) as obvious over TAMARKIN et al. (US Patent Application Publication 2005/0031547), in view of FRIEDMAN et al. (US Patent No. 5,744,155). Applicants respectfully traverse the rejection.

The instant application is a national stage application of PCT/EP04/011236, filed on October 8, 2004, and claims foreign priority to Italy Application No. MI2003A002019, filed on October 17, 2003. Applicants herein submit for the record a certified English language translation of the Italian priority document, thus perfecting a claim to the October 17, 2003, foreign priority date.

As recognized in the Office Action, TAMARKIN can qualify as a reference only under 35 U.S.C. § 102(e). TAMARKIN

was filed on April 28, 2004, prior to PCT/EP04/11236, but after the present application's October 17, 2003 foreign priority date. It also appears that TAMARKIN seeks priority to provisional application No. 60/492,385, filed on August 4, 2003, and provisional application No. 60/530,015, filed on Dec. 16, 2003. Thus, only provisional application No. 60/492,385 was filed prior to the present application's foreign priority date. This provisional application, however, cannot serve as a prior art reference against the present application.

The 35 U.S.C. § 102(e) critical reference date of a U.S. Patent or U.S. Application Publication is the filing date of the provisional application if the provisional application properly supports the subject matter relied upon to make the rejection in compliance with 35 U.S.C. § 112, first paragraph. In other words, the subject matter used in the rejection must be disclosed in the earlier-filed application in compliance with the written description and enablement requirements of 35 U.S.C. §112, first paragraph, in order for that subject matter to be entitled to the earlier filing date. (See, MPEP 2136.03). Provisional application No. 60/492,385 fails to meet these requirements.

An objective standard for determining compliance with the written description requirement is "does the description clearly allow persons of ordinary skill in the art

to recognize that he or she invented what is claimed?" *In re Gostelli*, 10 USPQ 2d 1614, 1618 (Fed. Cir. 1989). In other words, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date, he or she was in possession of the invention. The enablement requirement requires that the information contained in the disclosure of an application must be sufficient to inform those of skill in the relevant art how to make and how to use the claimed invention (*see*, MPEP 2136.02).

The Office Action relies on TAMARKIN for teaching emulsions and various features recited in instant claim 1, including an aqueous phase present at a concentration ranging from 0.5 to 2% by weight. An examination of the 60/492,385 provisional application, however, reveals that the document discloses compositions that are limited to:

- A) 2-5% hydrophobic solvent, 85-98% water;
- B) 5-10% hydrophobic solvent, 80-95% water;
- C) 10-20% hydrophobic solvent, 65-90% water; and
- D) 20-75% hydrophobic solvent, 25-75% water (*see*, pages 2-3, and Examples at pages 35-38 of the '385 provisional application). The 60/492,385 provisional application fails to teach or suggest any composition that includes an aqueous phase from 0.5 to 2% by weight, as recited in claim 1.

For at least this reason, TAMARKIN cannot serve as a 35 U.S.C. § 102(e) reference, as of the August 4, 2003, provisional application filing date, and cannot be cited against this particular subject matter in the claims of the present application. In addition, the present application's October 17, 2003, foreign priority date predates the December 16, 2003, filing date of the second provisional application, i.e., No. 60/530,015. Thus, TAMARKIN cannot serve as a reference under 35 U.S.C. § 103(a).

After having removed TAMARKIN as a reference, FRIEDMAN alone fails to teach or suggest a microemulsion having all of the features recited in claims 1, 3-5 and 8-16. Thus, for at least these reasons, TAMARKIN and FRIEDMAN fail to teach or suggest, and would not have rendered obvious, claims 1, 3-5 and 8-16. Applicants respectfully request reconsideration and withdrawal of the rejection.

At page 8, the Office Action rejects claims 5 and 6 under 35 U.S.C. § 103(a) as obvious over TAMARKIN, in view of FRIEDMAN, and further in view of BONDA (US Patent No. 6,551,605). Applicants respectfully traverse the rejection.

As detailed in the comments above, TAMARKIN cannot serve as a reference under 35 U.S.C. § 103(a). After having removed TAMARKIN as a reference, FRIEDMAN and BONDA, alone or in combination, fail to teach or suggest a microemulsion having all of the features recited in claims 5 and 6. Thus, for at least

these reasons, TAMARKIN and FRIEDMAN fail to teach or suggest, and would not have rendered obvious, claims 5 and 6. Applicants respectfully request reconsideration and withdrawal of the rejection.

IV. CONCLUSION

Having addressed all the outstanding issues, the amendment is believed to be fully responsive. Entry of the above amendments is earnestly solicited. Applicants respectfully request that a timely Notice of Allowance be issued in this case. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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APPENDIX:

- Certified copy of English language translation of the
Italian priority document